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Proposed Re-evaluation Decision

Sethoxydim

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Proposed Re-evaluation Decision

After a re-evaluation of the herbicide sethoxydim, under the authority of the *Pest Control Products Act*, Health Canada's *Pest Management Regulatory Agency* (PMRA) is proposing continued registration of sethoxydim products for sale and use in Canada.

An evaluation of available scientific information found that sethoxydim products do not present unacceptable risks to human health or to the environment when used according to label directions. As a condition of the continued registration of sethoxydim uses, new risk reduction measures must be included on the labels of sethoxydim products. Additional data are being requested as a result of this re-evaluation.

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products, to ensure they meet modern standards established to protect human health and the environment.

This proposal affects all end-use products containing sethoxydim registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This *Proposed Re-evaluation Decision* is a consultation document[1] that summarizes the science evaluation for sethoxydim and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides the technical information on the assessment of sethoxydim.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

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[1] "Consultation statement" as required by subsection 28 (2) - *Pest Control Products Act* 2002 (http://laws.justice.gc.ca/en/P-9.01/92455.html)

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Overview

What Does Health Canada Consider when Making a Re-evaluation Decision?

The PMRA is re-evaluating active ingredients and their uses to determine their continuing acceptability in relation to human health, environment and value. Sethoxydim is one of the active ingredients to be re-evaluated during the current re-evaluation cycle. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Sethoxydim has been re-evaluated under the Re-evaluation Program 1, which relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, there must exist a suitable foreign review that meets the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews, the PMRA will propose, under Program 1, a regulatory decision and appropriate risk reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account Canadian use pattern and issues (e.g. the Federal Toxic Substances Management Policy [TSMP]). A review of the chemistry of Canadian products is also conducted.

The USEPA conducted a re-evaluation of sethoxydim, and conclusions of this re-evaluation are published in a 2005 RED. On the basis of health and environmental risk assessments, the USEPA concluded that sethoxydim was eligible for reregistration. Based on the comparison of American and Canadian use patterns, the USEPA assessments described in this RED document were considered an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What is Sethoxydim?

Sethoxydim is a herbicide used to control weeds on many food/feed crops and on creeping red fescue for seed production, on flax for industrial and fibre production, on shelterbelts of chokecherry and on ornamental trees and shrubs. Sethoxydim is applied using ground equipment, such as groundboom, or aerial equipment by farm workers, professional applicators and homeowners.

Health Considerations

Can Approved Uses of Sethoxydim Affect Human Health?

Additional risk reduction measures are required on sethoxydim labels. Sethoxydim is unlikely to affect your health when used according to revised label directions.

Exposure to sethoxydim may occur through food and water, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that sethoxydim was unlikely to affect human health, provided that risk reduction measures were implemented. These conclusions were considered applicable to the Canadian situation, and equivalent risk reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Sethoxydim is currently registered in Canada for use on asparagus, carrot, potatoes, sweet potatoes, sugar beets, turnip, Chinese radish, garlic, onion, spinach, mustard greens, broccoli, cabbage, cauliflower, Chinese broccoli, napa cabbage, kohlrabi, mustard cabbage, beans, soybeans, lentils, peas, snow peas, chickpeas, tomatoes, peppers, cucumbers, pumpkins, squash, bearing and non-bearing fruit trees, highbush blueberries, raspberries, cranberries, strawberries, buckwheat, mint, caraway, dill, coriander, mustard seed, canola/rapeseed, safflower, flax, sunflowers, hops and forage legumes.

Sethoxydim may be used in other countries on other crops imported into Canada. Where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm, which is considered a general MRL for enforcement purposes.

MRLs for sethoxydim are established for the following commodities: lentils at 30 ppm; tomato paste at 15 ppm; dry beans, peas and strawberries at 10 ppm; sunflowers at 7 ppm; beans, raspberries and soybeans at 5 ppm; blueberries, potatoes and tomatoes at 4 ppm; artichokes, cabbage, cantaloupes, cranberries, eggplants, eggs, mustard, mustard greens and spinach at 2 ppm; celery, cucumbers, lettuce, pumpkins and squash at 1 ppm; asparagus, broccoli, corn, peppers and liver of poultry at 0.5 ppm; flax, onions, meat of poultry and turnips at 0.2 ppm; and carrots at 0.1 ppm.

Changes to the general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be promulgated.

Environmental Considerations

What Happens When Sethoxydim is Introduced Into the Environment?

Additional risk reduction measures are required on sethoxydim labels. Sethoxydim is unlikely to affect non-target organisms when used according to revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) may be exposed to sethoxydim in the environment. Environmental risk is assessed by the risk quotient method, in which a risk quotient (RQ) is calculated as the ratio of the estimated environmental concentration (EEC) to the relevant effects endpoint of concern. The resulting RQs are compared to corresponding levels of concern (LOCs). An RQ less than the LOC is considered a negligible risk to non-target organisms, whereas an RQ greater than the LOC indicates some degree of risk.

The USEPA concluded that the reregistration of sethoxydim was acceptable provided risk reduction measures to further protect the environment were implemented. These conclusions were considered applicable to the Canadian situation, and equivalent risk reduction measures are required. Furthermore, the PMRA will require aquatic and terrestrial buffer zones for sethoxydim to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Registered pesticide product labels contain specific directions for use which include risk reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of sethoxydim, further risk reduction measures are proposed in addition to those already identified on existing sethoxydim product labels. These additional measures are designed to further protect human health and the environment, and are summarized as follows:

Human Health

- To protect workers re-entering treated sites: restricted entry interval

Environment

- To reduce potential surface and groundwater contamination: additional advisory label statements
- To protect non-target sensitive species: Buffer zones for aquatic and terrestrial habitats.

What Additional Scientific Information is Being Requested?

Data are required as a condition of continued registration under Section 12 of the PCPA. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent to registrants of the technical active ingredients by the PMRA.

The PMRA based buffer zone calculations on limited toxicity data, so buffer zones required in this document are interim. Data are being requested to confirm that the proposed interim aquatic buffer zones adequately protect sensitive habitats.

Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on sethoxydim, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a *Re-evaluation Decision*[2] document which will include the decision, the reasons for it, a summary of comments received on the proposed decision, and the PMRA's response to these comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act* (http://laws.justice.gc.ca/en/P-9.01/92455.html)

Science Evaluation

1.0 Introduction

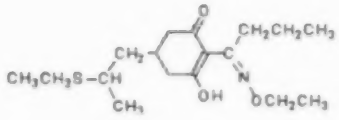
Sethoxydim is a selective systemic herbicide which acts by the inhibition of fatty acid synthesis.

Following the re-evaluation announcement for sethoxydim, the registrant of the technical grade active ingredient in Canada indicated they would continue to support all uses included on the labels of commercial and domestic end-use products.

The PMRA used recent assessments of sethoxydim from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for sethoxydim, dated 30 September 2005, as well as other information on the regulatory status of sethoxydim in the United States, can be found on the USEPA's website at www.regulations.gov/fdmspublic/component/main.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common Name:	Sethoxydim
Function:	
Chemical Family:	Cyclohexanedione oxime
Chemical Name:	
1 **International Union of Pure and Applied Chemistry (IUPAC):**	(5*RS*)-(*EZ*)-2-(1-ethoxyiminobutyl)-5-[(2*RS*)-2-(ethylthio) propyl]-3-hydroxycyclohex-2-en-1-one
2 **Chemical Abstracts Service (CAS):**	2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydro xy-2-cyclohexen-1-one
CAS Registry Number:	74051-80-2
Molecular Formula:	$C_{17}H_{29}NO_3S$
Molecular Mass:	327.5 amu
Structural Formula:	
Registration Number:	19053

Purity of the Technical Grade Active Ingredient: 50% nominal concentration

Nitrosamine analysis was done in 1986 for diethylnitrosamine (NDEA). None was measured at a limit of detection (LOD) of 0.03 ppm. Based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Results
Vapour pressure	4.55×10^{-10} mm Hg at 25°C
UV absorption	Not expected to absorb UV at $\lambda > 300$ nm. Maximum absorption appears at 285 nm.
Solubility in water (20°C)	25 mg/L at pH 4; 4700 mg/L at pH 7
***n*-octanol-water partition coefficient**	pH: 5, 7 $\log K_{ow}$: 4.51, 1.65

2.3 Comparison of Use Patterns in Canada and the United States

Sethoxydim is a selective systemic herbicide for the control of annual and perennial grasses and broadleaved weeds. It acts by inhibition of fatty acid synthesis, i.e. inhibits the acetyl CoA carboxylase and mitosis. It is registered in Canada for use on food and feed crops[3], industrial oil seed and fibre crops (creeping red fescue and flax), forestry and woodlots (shelterbelts of chokecherry), and ornamentals (trees and shrubs, and shelterbelts of chokecherry). Sethoxydim is applied post-emergent to weeds at early stages of growth. It is typically applied only once per growing season at a maximum of 0.5 kg a.i./ha using ground or aerial equipment. A second application is possible, 7–10 days later, using the same application rate. The end-use products are formulated as emulsifiable concentrates and are applied using ground and aerial equipment.

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[3] Asparagus, carrot, potatoes, sweet potatoes, sugar beets, turnip, Chinese radish, garlic, onion, spinach, mustard greens, broccoli, cabbage, cauliflower, Chinese broccoli, napa cabbage, kohlrabi, mustard cabbage, beans, soybeans, lentils, peas, snow peas, chickpeas, tomatoes, peppers, cucumbers, pumpkins, squash, bearing fruit trees, non-bearing fruit trees, highbush blueberries, raspberries, cranberries, strawberries, buckwheat, mint, caraway, dill, coriander, mustard seed, canola/rapeseed, safflower, flax, sunflower as well as hops and forage legumes for seed and forage.

A comparison of use patterns in Canada and the United States (US) was conducted. Sethoxydim is formulated as an emulsifiable concentrate in both the US and Canada and the Canadian maximum application rate (0.5 kg a.i./ha) and number of applications (maximum of two applications per year) are encompassed by the US use pattern (0.5 kg a.i./ha and maximum of four applications per year). Canadian and US application methods include the use of ground and aerial equipment. Some use sites are unique to Canada[4]; however, the US use pattern is more extensive than that of Canada and includes other sites such as rights-of-way, roadsides, tobacco, residential lawns, and other food/feed crops[5]. Based on this comparison of use patterns, it was concluded that the USEPA RED for sethoxydim is an adequate basis for the re-evaluation of Canadian uses of sethoxydim.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation of sethoxydim. Appendix II lists all sethoxydim products that are registered under the authority of the PCPA.

3.0 Impact on Human Health and the Environment

The USEPA conducted a re-evaluation of sethoxydim and published its conclusions in a 2005 RED. It concluded that the end-use products formulated with sethoxydim met the safety standard under the US *Food Quality Protection Act* (FQPA) amendments and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended labels of all end-use products containing sethoxydim.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to the effects of a chemical than the most sensitive animal species.

Exposure to sethoxydim may occur through consumption of food and water, residential exposure, working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

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4 **Canadian uses not registered in the US:** turnip, Chinese radish, snowpeas, chickpea, buckwheat, caraway, dill, coriander, mustard seed, hops, *Cicer milkvetch* and shelterbelts of choke cherry.

5 **US food/feed crops not registered in Canada:** corn, celery, lettuce, leek, ginger, parsley, radicchio, Brussel sprouts, eggplants, cantaloupes, melons, and citrus, shallot, amaranth, arugula, cardoon, celtuce, chervil, chrysanthemum, cress, dandelion, fennel, orach, purslane, Swiss chard, crabapple, prune, pomegranate, pepino, ground cherry, tomatillo, lingonberry, loganberry and youngberry.

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures, using the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but measures to mitigate risk would be required. The toxicological endpoints selected by the USEPA for assessment of risk from occupational exposure are summarized in Appendix III.

Workers can be exposed to sethoxydim through mixing, loading or applying the pesticide, and when re-entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

No dermal short-term or intermediate endpoints of concern were identified by the USEPA, and sethoxydim was classified as "not likely to be carcinogenic to humans". Therefore no occupational risk assessments were conducted for these routes of exposure.

Three potential exposure scenarios for handlers were assessed by the USEPA which are applicable to the Canadian use pattern:

- Mixing/loading liquids for groundboom or aerial application
- Applying sprays using groundboom or aerial equipment
- Mixing/loading/applying liquids using low pressure handwand

Handler exposure analyses were performed using the Pesticide Handlers Exposure Database (PHED), assuming baseline personal protective equipment (PPE) of a long-sleeved shirt, long pants and no gloves. Short-term and intermediate inhalation exposure risk was based on a maximum sethoxydim application rate of 0.52 kg a.i./ha, and a no observed adverse effect level (NOAEL) of 81 mg/kg/bw/day from a 28-day rat inhalation study (target margin of exposure (MOE) = 100).

The USEPA reported acceptable short-term and intermediate MOEs for these occupational exposure scenarios, ranging from 8400 to 1 900 000. Based on these quantitative risk assessments, no additional risk reduction measures were required for the protection of handlers.

The RED adequately addressed potential exposure scenarios associated with the Canadian uses of sethoxydim, and thus conclusions were considered applicable to the Canadian situation. Currently, Canadian end-use product labels include recommendations for PPE such as goggles/face shield, chemical-resistant gloves, etc. These were considered adequate. Additional instructions concerning good hygiene practices are required on labels. The proposed label amendments are listed in Appendix IV.

3.1.1.2 Postapplication Exposure and Risk

The USEPA did not assess occupational postapplication risks to agricultural workers because no dermal endpoint of concern was established, and postapplication inhalation exposure was expected to be negligible.

The 1992 USEPA Worker Protection Standard (WPS) is designed to reduce the number of injuries from handling pest control products. A restricted-entry interval (REI) is the period of time following a pesticide application during which workers are not allowed to re-enter the treated area. According to the WPS, the length of the REI is determined by the toxicity of the active ingredient. In lieu of a postapplication risk assessment, a REI of 12 hours for all sethoxydim agricultural use products was required as per the WPS.

This was considered applicable to the Canadian situation, and the PMRA requires a 12-hour REI for all uses to further protect workers from postapplication exposure. Proposed label amendments are listed in Appendix IV.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure and Risk

Residential exposure is estimated using the MOE approach as explained for the occupational exposure and risk assessment in section 3.1.1. The toxicological endpoints selected by the USEPA for assessment of risk from residential exposure are summarized in Appendix III.

Homeowners can be exposed to sethoxydim through mixing, loading and applying the pesticide, and when re-entering a treated site. Toddlers can be exposed via hand-to-mouth and object-to-mouth activities, and through incidental soil ingestion.

In the US, sethoxydim is registered for use on ornamental and flowering plants, on lawns and around buildings/structures. Short-term risks to adults from handling via dermal and inhalation exposure, and short-term risk to toddlers from incidental oral exposure, were assessed. Handler exposure analyses were performed using PHED data for backpack sprayer and low-pressure handwand application, and Outdoor Residential Exposure Task Force (ORETF) handler studies for garden hose attachment sprayer application based on assumed application rates of 0.5 kg a.i./ha and 2.4 g a.i./L. Acceptable adult handler short-term inhalation MOEs ranging from 1 400 000 to 1 600 000 (target MOE = 100), and toddler incidental oral MOEs ranging from 26 000 to 7 600 000, were reported (target MOE = 100).

In Canada, sethoxydim is only registered as a commercial product. Therefore, there is no application by homeowners. However, some commercial uses may result in application in residential areas, such as the use on ornamental trees and shrubs, and may be associated with potential residential postapplication exposure. Thus, conclusions derived in the RED are considered applicable to the Canadian situation.

3.1.2.2 Exposure From Food and Drinking Water

Acute dietary risk is calculated based on the highest ingestion of sethoxydim that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of sethoxydim residues that might be consumed in a day. A value representing the high end (99.9th percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. This ARfD is based on a relevant endpoint from toxicology studies. The acute population-adjusted dose (aPAD) is the ARfD adjusted for the FQPA safety factor to be protective of the most sensitive subpopulation (see Appendix III). When the expected intake of residues is less than the aPAD, then the acute dietary exposure is considered to be acceptable by the USEPA.

A Tier II acute dietary risk assessment due to risk from residues in food was conducted using Dietary Exposure Evaluation Model (DEEM)-Food Commodity Intake Database (FCID) analysis, which incorporates food consumption data from the United States Department of Agriculture's Continuing Survey of Food Intake by Individuals (CSFII), 1994–1996, 1998, resulting in 9.2% of the aPAD for children 1 to 2 years old and children 3–5 years old, the most sensitive subpopulations. This assessment was based on an aPAD of 1.8 mg/kg/bw/day, which was calculated from a rat developmental toxicity study (NOAEL of 180 mg/kg/bw/day with an uncertainty factor (UF) of 100× and a FQPA safety factor of 1×). These risk estimates from food exposure were generated assuming tolerance-level residues for most crops (for crops considered more highly associated with dietary exposure to sethoxydim, field trial data were used), tolerance level residues for meat, poultry, milk and eggs, and percent crop treated used for most crops (100% crop treated when no information was available).

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to a chronic reference dose (cRfD), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. This cRfD is based on a relevant endpoint from toxicology studies. The chronic population-adjusted dose (cPAD) is the cRfD adjusted for the FQPA safety factor to be protective of the most sensitive subpopulation (see Appendix III).When the expected intake of residues is less than the cPAD, then chronic dietary exposure is considered acceptable by the USEPA.

A Tier II chronic dietary risk assessment due to risk from residues in food was conducted using the DEEM model, resulting in 7.5% of the cPAD for infants less than one year old, the most sensitive subpopulation. This assessment was based on a cPAD of 0.14 mg/kg bw/day, which was calculated from a chronic toxicity/carcinogenicity study in mice (NOAEL of 13.8 mg/kg bw/day (UF = 100× and FQPA Safety Factor = 1×). These risk estimates from food exposure were generated assuming tolerance-level residues for all crops, percent crop treated for many crops, and anticipated residues for meat and milk.

Exposure to pesticides through drinking water can occur as a result of groundwater or surface water contamination. Both acute (one day) and chronic (multiple year) drinking water risks are considered, using either modelling or actual monitoring data, if available, to estimate those risks. Modelling is carried out in tiers of increasing refinement, but is designed to provide high-end estimates of exposure. The risk assessment may be conducted by the "drinking water level of comparison" (DWLOC) approach or assessed probabilistically in DEEM/Lifeline.

For sethoxydim, drinking water exposure was addressed by calculating DWLOCs. To determine the maximum allowable contribution from water in the diet, the overall risk contributed by food was first established; then the DWLOC was determined. The DWLOC represents the maximum allowable contribution to the human diet that may be attributed to residues of a pesticide in drinking water after dietary exposure is subtracted from the aPAD or cPAD.

Sethoxydim was found to be highly soluble and mobile; however, because it is not persistent, sethoxydim was not expected to contaminate ground or surface waters. For the most sensitive subpopulations outlined above, the acute DWLOC was determined to be 16 400 parts per billion (ppb), and the chronic DWLOC was determined to be 1300 ppb. Estimated drinking water concentrations (EDWC) were generated using Tier I models, i.e. FQPA Index Reservoir Screening Tool (FIRST) for surface water and Screening Concentration Ground Water (SCI-GROW) for groundwater. Based on four applications of 0.5 kg a.i./ha applied at 14-day intervals, the resulting EDWCs for surface water were 130 ppb for acute exposure and 16 ppb for chronic exposure. Based on one application of 2.1 kg a.i./ha, resulting EDWC for groundwater was 1.5 ppb for both acute and chronic exposures. Because the EDWCs were much lower than the DWLOCs, dietary (food plus drinking water) risk was found to be acceptable, and no mitigation with respect to dietary risk was required.

Many US food/feed crop uses are common to Canadian uses[6]. However, there are some differences, and the USEPA risk from food exposure assessment did not include all Canadian food/feed crop uses[7] but included uses not registered in Canada[8]. Despite the different use patterns in the US and Canada, this assessment is considered to be relevant to Canada because their Tier II estimates of exposure from food residues filled only a small portion of the risk cup, representing 9.2% of the aPAD and 7.5% of the cPAD, for the most sensitive subgroups, and EDWCs were much lower than the DWLOCs (based on higher seasonal application rates than registered in Canada of 1.0 kg a.i./ha).

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to sethoxydim (i.e. from food, water and residential exposures). Acute and chronic aggregate risk assessments are comprised of contributions from food and drinking water exposures. Short-term and intermediate aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation).

Acute and chronic non-occupation exposures were not expected. As a result, acute and chronic aggregate risks were considered to be equal to acute and chronic dietary risks, as outlined in Section 3.1.2.2.

Short-term aggregate risk assessments were not calculated for adult handlers because oral and inhalation endpoints lacked a common toxicity endpoint. For short-term exposure to children and toddlers, estimates of postapplication exposure scenarios (children/toddlers oral and inhalation exposures after turf applications) were combined with dietary exposure. For dietary exposure, children aged 1–2 yrs were identified as the most sensitive subgroup due to having the "highest estimated food exposure". Short-term aggregate risk was found to be acceptable with a short-term MOE greater than the target MOE, and DWLOC of 17 800 ppb for the most sensitive subgroup compared to the chronic EDWCs of 16 ppb for surface water and 1.5 ppb for groundwater.

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6 **US and Canadian common food/feed uses:** asparagus, carrot, potatoes, sweet potatoes, sugar beets, garlic, onion, spinach, mustard greens, broccoli, cabbage, cauliflower, Chinese broccoli, napa cabbage, kohlrabi, mustard cabbage, beans, soybeans, lentils, peas, tomatoes, peppers, cucumber, pumpkins, squash, apricot, apple, cherry, peach, pear, plum, non-bearing fruit trees, blueberry, raspberry, strawberry, canola/rapeseed, flax, safflower, sunflower, alfalfa, clover, sainfoin and chickling vetch.

7 **Canadian food/feed uses not registered in the US:** turnip, Chinese radish, snowpeas, chickpea, buckwheat, caraway, dill, coriander, mustard seed, hops, Cicer milkvetch.

8 **US food/feed uses not registered in Canada:** corn, celery, lettuce, leek, ginger, parsley, radicchio, Brussel sprouts, eggplants, cantaloupes, melons, and citrus, shallot, amaranth, arugula, cardoon, celtuce, chervil, chrysanthemum, cress, dandelion, fennel, orach, purslane, Swiss chard, crabapple, prune, pomegranate, pepino, ground cherry, tomatillo, lingonberry, loganberry, youngberry and cotton.

Overall, the Canadian potential aggregate exposure scenarios were adequately addressed by the USEPA aggregate risk assessment. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of sethoxydim in Canada.

3.1.3 Cumulative Effects

The USEPA has not determined whether sethoxydim has a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that sethoxydim does not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

It was reported in the RED that four transformation products of sethoxydim were expected in the environment, i.e. the sulfoxide and sulfone derivatives of the parent (MSO and MSO2), 2-(1-aminobutylidene)-5-[2-(ethylthio)-propyl]-cyclohex-1,3-dione (M1S) and 6-[2-(Ethylthio)propyl]-4-oxo-2-propyl-4,5,6,7-tetrahydrobenzoxazole (M2S). Because of limited data available on these transformation products, they were assumed "as toxic as the parent to ensure that risk will not be underestimated". Therefore, USEPA conclusions on environmental risk included the parent compound plus the four transformation products.

Sethoxydim, *per se,* was found to be highly soluble in water and mobile; however, because it is not persistent, contamination of surface or groundwaters was not expected. Sethoxydim transformation products (MSO, MSO2, M1S, and M2S) were determined to be persistent and mobile and to have the potential to contaminate water resources.

To assess the ecological risk of sethoxydim to both terrestrial and aquatic non-target plants and animals, the USEPA calculated RQs based on appropriate toxicity endpoints and EECs and compared the resulting RQs to LOCs.

Sethoxydim was found to be practically non-toxic to birds and terrestrial mammals on acute and chronic bases, and to be practically non-toxic to terrestrial insects on an acute basis. Risk was not of concern for these groups of species at rates relevant to the Canadian use pattern, i.e. 1 or 2 applications of 0.5 kg a.i./ha.

The technical grade active ingredient for sethoxydim was determined to be practically non-toxic to freshwater and marine/estuarine fish and invertebrates, and the end-use products containing sethoxydim were determined to be moderately toxic to these species. The presence of a solvent (naphthalene) in the US end-use products was considered to be responsible for this higher toxicity of the end-use products. Although acute and chronic risks from exposure to the technical or end-use products were determined not to be of concern, confirmatory testing using the end-use product was required by the USEPA for aquatic species and terrestrial plants to refine the risk assessment.

Tier II terrestrial plant EECs were calculated based on one application of 0.53 kg a.i./ha, using the TerrPlant model for runoff exposure and the AgDrift model for spray drift exposure. Tier II acute RQs from spray drift exceeded the LOC of 1.0 for aerial application from edge of field up to 50 feet for non-listed species and up to 100 feet for listed species (RQs = 0.2–9.4). For acute risk from runoff to low semi-aquatic areas, RQs exceeded LOCs for listed and non-listed plant species (RQs = 1.3–4.1; LOC = 1.0).

Aquatic non-target plant EECs were generated from the Generic Expected Environmental Concentration (GENEEC) model. For all exposure scenarios, the assumed maximum application rate was four applications at 0.5 kg a.i./ha. Acute risk was found to be acceptable for aquatic vascular dicots. Additional data were required to assess risk to aquatic monocots. Also, since the end-use product was determined to potentially be more toxic than the technical, additional testing on terrestrial and aquatic plants using the end-use product was required.

Scenarios assessed by the USEPA are relevant to the Canadian situation, and the RED is considered to be an adequate basis for the re-evaluation of sethoxydim. The USEPA did not require any additional risk reduction measures to further protect the environment.

The PMRA will require terrestrial and aquatic buffer zones for sethoxydim to protect aquatic organisms and terrestrial plants from spray drift. Proposed label amendments are listed in Appendix IV. Inputs to buffer zone models are described in Appendix V. Resulting aquatic and terrestrial buffer zone distances are included in the label amendments listed in Appendix IV. These buffer zones were based on USEPA endpoints and may be underestimated. According to the USEPA conclusions, monocot plants are more sensitive (no aquatic monocot plant testing was available) and the US end-use product seemed more toxic than the technical, although data were limited as an insufficient number of species were tested using the US end-use products. Consequently, buffer zones required in this document are interim. Data are required to confirm that the proposed interim buffer zones adequately protect sensitive aquatic and terrestrial habitats. Appendix I lists all data requirements.

To reduce contamination of surface and groundwaters from spray drift and runoff, additional label statements are required. The proposed label amendments are listed in Appendix IV.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's *Toxic Substances Management Policy* (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and which could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The Federal Toxic Substances Management Policy and the Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of sethoxydim and the following was concluded:

- Sethoxydim is not bioaccumulative; the *n*-octanol–water partition coefficient (log K_{ow}) for sethoxydim is 4.51 at pH 5 and 1.65 at pH 7, which are below the TSMP Track 1 cut-off criterion of 5.0, and the calculated bioconcentration factor (BCF) is 21× for the whole fish, which is below the TSMP Track 1 cut-off criterion of 5000×. Sethoxydim does not meet all Track 1 criteria, and thus it is not a candidate for Track 1 classification.

- Based on a review of the available chemistry information (see Section 2.1), the technical product is not expected to contain impurities of toxicological concern as identified in Regulatory Directive DIR98-04 or TSMP track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II.

- Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

4.0 Proposed Regulatory Decision

The PMRA has determined that sethoxydim is acceptable for continued registration with the implementation of the proposed risk reduction measures. These measures are required to further protect the human health and environment. Canadian end-use product labels should be amended to include label statements listed in Appendix IV. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. The registrant of the technical active ingredient is required to submit data as a condition of continued registration under Section 12 of the PCPA. Appendix I lists data requirements.

5.0 Supporting Documentation

PMRA documents, such as DIR2001-03 and DACO tables, can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); Fax: 613-736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca.

Canadian MRLs established in Food and Drugs Regulations are available on the Department of Justice Canada's website at www.justice.gc.ca

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document (Sethoxydim, EPA Case No. 2600) is available on the 'Office of Pesticide Programs' website at www.regulations.gov/fdmspublic/component/main.

List of Abbreviations

µg	microgram
ADI	acceptable daily intake
a.i.	active ingredient
aPAD	acute population adjusted dose
ARfD	acute reference dose
ARI	aggregate risk index
ARTF	Agricultural Re-entry Task Force
atm	atmosphere(s)
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
cPAD	chronic population adjusted dose
cRfD	chronic reference dose
CSFII	Continuing Survey of Food Intakes by Individuals
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DT_{50}	dissipation time to 50%
DWLOC	drinking water level of comparison
EDWC	estimated drinking water concentration
EEC	expected environmental concentration [also estimated environmental concentration]
EXAMS	Exposure Analysis Modeling System
FIRST	FQPA Index Reservoir Screening Tool
FQPA	*Food Quality Protection Act*
g	gram(s)
ha	hectare
IRED	Interim Reregistration Eligibility Decision
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LEACHM	Leaching Estimation and Chemistry Model
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEC	lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
LOEL	lowest observed effect level
m	metre(s)
m^3	metre(s) cubed
mg	milligram(s)

mm	millimetre(s)
mm Hg	millimetre mercury
MOE	margin of exposure
MRL	maximum residue limit
nm	nanometre
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PCPA	*Pest Control Products Act*
PDI	potential daily intake
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
PIC	Prior Informed Concent
p*K*a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
Q_1^*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RfD	reference dose
RVD	Re-evaluation Decision
RQ	risk quotient
SCI-GROW	Screening Concentration in Ground Water
TC	transfer coefficient
TGAI	technical grade active ingredient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Data Requirements for Sethoxydim

The following data are required as a condition of continued registration under Section 12 of the PCPA. The registrants of this active are required to provide these data within the timeline specified in the decision letter that will be sent to registrants of the technical active ingredient by the PMRA:

- DACO 9.3.5 – Non-target Freshwater Invertebrates - Laboratory studies with End-use product; Chronic (life cycle) test with *Daphnia* sp.
- DACO 9.5.4 – Fish - Laboratory Studies with End-use Product; Fish early life stage toxicity test conducted with rainbow trout.
- DACO 9.8.6 – Non-target Plants - Laboratory Studies with End-use Product; Tier II vegetative vigour and seedling emergence studies and Tier II aquatic vascular studies.

These studies must be conducted with a Canadian end-use product or a product with equivalent formulation and guarantee and be conducted according to the appropriate USEPA Office of Prevention, Pesticides and Toxic Substances or Organisation for Economic Co-operation and Development guidelines. Should the registrant fail to submit these studies within the specified timeline, in place of the interim buffer zones, conservative buffer zones for the protection of sensitive terrestrial and aquatic habitats will be required on product labels.

Appendix II Registered Sethoxydim Products as of 11 June 2007

Registrant	Registration Number	Guarantee	Product Name	Formulation Type	Class
BASF Canada Inc.	19053	50% (w/w)	BASF Poast Herbicide Manufacturing Concentrate	Not available	Technical
BASF Canada Inc.	24835	450 g / L	Poast Ultra Liquid Emulsifiable Herbicide	Emulsifiable Concentrate	Commercial
BASF Canada Inc.	25820	450 g / L	Poast Ultra (A Component of FlaxMax) Herbicide Tank Mix	Emulsifiable Concentrate	Commercial
BASF Canada Inc.	*17502**	184 g / L	*BASF Poast Liquid Emulsifiable Herbicide**	Emulsifiable Concentrate	Commercial
BASF Canada Inc.	*24416**	184 g / L	*Poast (a component of flaxmax) herbicide tank Mix**	Emulsifiable Concentrate	Commercial

* Discontinued products (Discontinued date: 31 December 2005; Expiry Date: 31 December 2007)

Appendix III Toxicological Endpoints Selected by the USEPA for the Sethoxydim Health Risk Assessment

Exposure Scenario	Dose (mg /kg bw/day)	Study	Endpoint and UF/FQPA SF
Dietary acute	NOAEL = 180	Developmental toxicity study in rat	UF = 100× ARfD = 1.8 mg/kg bw/day FQPA SF = 1× **aPAD = 1.8 mg/kg bw/day**
Dietary chronic	NOAEL = 14	Carcinogenicity study in the mouse	UF = 100× cRfD = 0.14 mg/kg/bw/day FQPA SF = 1× **cPAD = 0.14 mg/kg bw/day**
Incidental oral short-term	NOAEL = 180	Developmental toxicity study in rat	UF = 100× **target MOE (residential) = 100**
Inhalation short-term	NOAEL = 81	28-day inhalation study in the rat	UF = 100× **target MOE (residential) = 100** **target MOE (occupational) = 100**
Carcinogenicity	"not likely to be a human carcinogen"		

NOAEL = no observed adverse effects level; RfD = reference dose; aPAD = acute population-adjusted dose; cPAD chronic PAD; UF = uncertainty factor; FQPA SF = Food Quality Protection Act safety factor; MOE = margin of exposure.

Appendix IV Label Amendments for Products Containing Sethoxydim

Canadian end-use product labels must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in a section entitled **"PRECAUTIONS"**:

- "Do not apply this product in a way that will cause this product to contact workers or other persons, either directly or through drift. Only handlers (mixers, loaders and applicators) wearing personal protective equipment may be in the area being treated during application."
- "Do not enter or allow entry into treated areas during the restricted-entry interval (REI) of 12 hours."

II) The following statements must be included in a section entitled **"DIRECTIONS FOR USE"**:

- "Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification."
- "When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture."

III) The following statements must be included in a section entitled **"DIRECTIONS FOR USE"** section of the end-use product PCP No. 25820 label:

- "DO NOT apply by air."
- "**Buffer zones:** The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands)."

Method of application	Buffer Zones (metres) Required for the Protection of Terrestrial Habitats
Field sprayer	1

IV) The following statements must be included in a section entitled **DIRECTIONS FOR USE** section of the end-use product PCP No. 24835 label:

- "Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. DO NOT allow nozzle spacing to exceed 65% of boom length."

- "**Buffer zones:** The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats."

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:		
			Aquatic Habitats of Depths:		Terrestrial Habitats
			Less than 1 m	Greater than 1 m	
Field sprayer	All crops		0	0	1
Aerial	Food / feed crops	Fixed wing	0	0	60
		Rotary wing	0	0	50
	Non-croplands, orchards, ornamental trees, shelterbelts	Fixed wing	55	0	200
		Rotary wing	40	0	150

V) The following statements must be included in a section entitled **"ENVIRONMENTAL HAZARD"**:

- "TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE."

- "This product contains a petroleum distillate which is moderately to highly toxic to aquatic organisms. Avoid contamination of aquatic systems during application."

- "Do not apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), estuaries or marine habitats."

- "Do not contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

- "To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include, but are not limited to: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine textured such as clay)."

- "Avoid application of this product when heavy rain is forecast."

- "Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements. A submission to request label revisions is required within 90 days of finalization of the re-evaluation decision.

Appendix V Inputs to Buffer Zone Models for Sethoxydim

Ground Use Data (From Canadian labels)					
Crop	Formulation Type	Method of Application	Number of Applications	Maximum Application Rate	Minimum interval between applications
All ground uses	Emulsifiable concentrate	Field (medium)	2	500 g a.i./ha	7 days

Aerial Use Data (From Canadian labels)					
Corps	Formulation Type	PCP Number	Number of Applications	Maximum Application Rate	Minimum interval between applications
Food/Feed crops	Emulsifiable concentrate	24835	2	500 g a.i./ha	7 days
Non-croplands, orchards, and ornamental trees	Emulsifiable concentrate	24835	2	500 g a.i./ha	7 days

Product Information for Aerial Use	
Parameter	Value
	PCP #24835
Aircraft type	Fix&Rot wing
ASAE spray quality	Medium
Carrier	Water
Product guarantee (g a.i./L)	450
Specific gravity of end-use product (g/L)	970
Minimum spray volume (L/ha)	25
Water content of product (%)	0
Wind speed (km/h)	16
Temperature (°C)	25
Relative humidity (%)	50

Model Input Data for Aquatic Buffer Zones (from 2005 RED)		
Half life for aquatic buffer zones	Aerobic aquatic metabolism	38 days
Choice of toxicity endpoint for amphibian buffer zones	Rainbow trout	1/10 EC_{50} = 0.12 mg/L
Choice of toxicity endpoint for freshwater buffer zones	Rainbow trout	1/10 EC_{50} = 0.12 mg/L
Choice of toxicity endpoint for marine buffer zones	Marine diatom	½ EC_{50} = 0.125 mg/L

Model Input Data for Terrestrial Buffer Zones (from 2005 RED)		
Half life for terrestrial buffer zones	Terrestrial field dissipation in two locations in California (cotton and forage)	32 days
Most sensitive terrestrial plant species EC_{25}	Vegetative vigor, ryegrass	33 g/ha